

REMARKS

On the first page of the Action (Office Action Summary), it is stated that claims 1-17 were pending and addressed, with claims 1-7 and 10 being allowed and claims 8 and 11-17 being rejected. There is no mention on this page of claim 9. However, it is understood that claim 9 is allowed as well, since claims 1-7 and 9-10 are said to be allowable at page 5 of the Action.

The Examiner states at page 2 of the Action that the section 112, second paragraph rejection of claim 10 is withdrawn, and, as noted above, claim 10 is indicated as being allowed and allowable at pages 1 and 5 of the Action. However, claim 10 was cancelled (without prejudice) in the Amendment and Response filed February 24, 2003 as being in a "use" form not generally accepted under U.S. practice. The specific withdrawal of the rejection of claim 10, and the allowance of cancelled claim 10 is therefore not understood. Claim 10 was replaced by new claims 11-17, which are in proper and generally accepted method form. While it might be understood that the Examiner intended to state that one or more of the replacement method claims was allowed, rather than claim 10, the Examiner has specifically rejected claims 11-17. Therefore, clarification of the statements expressly allowing claim 10 is requested.

Process claim 8 remains rejected under 35 U.S.C. § 112, first paragraph, as being "based on a disclosure which is not enabling." The rejection continues:

The steps involved in removing any protective groups critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure is missing. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The applicant does not disclose the steps involved in removing any protective groups from the compound.

This ground for rejection is respectfully traversed.

First of all, the *Mayhew* case is not in any way applicable to the circumstances here presented. In *Mayhew*, applicants invention was described as a method for producing a galvanized steel strip which employed a "cooling zone . . . at the point where the steel strip exits from the bath." Applicant taught that without the cooling zone at the exit side of the bath, (in the Court's words) "the unusually high bath temperature would cause alloying to continue when the strip leaves the bath (due to its high temperature) and result, for various reasons, in an inferior alloy coating." However, a number of the claims did not recite this cooling zone at all, or its location at the exit of the bath. Applicant attempted to argue that the cooling bath was optional, but the Court (as well as the examiner and the Board), found "that both it and its location are essential." The Court held that "the claims failing to recite the use of a cooling zone, specially located, are not supported by an enabling disclosure."

In the present application, the step of removing the protective groups is specifically recited in step i) of the claim. Moreover, the removal of any protective groups is clearly disclosed in the specification as being optional, for example at page 7, line 4-6 it is stated "and thereafter, if necessary: . . . ii) removing any protecting groups." Thus, at the very least, the present circumstances are totally distinguishable from the circumstances and holding in *Mayhew* in that the removal of protective groups is optional ("if necessary") and certainly not essential as in *Mayhew*, and the optional step of removing the protecting groups is, in any event, specifically recited in claim 8. The basis for the Court's holding in *Mayhew*, to the contrary, was that the cooling step and its location were disclosed as been essential, and not optional, and this essential step was not recited in the claims for which the rejection was sustained.

It is therefore not seen how *Mayhew* could possibly support the rejection of claim 8, which specifically recites the non-essential (e.g., optional) step of removing the leaving groups. If this ground for rejection is maintained, an explanation of how the rejection is supported by the case law is respectfully requested so that the issue can be properly framed if an appeal is taken.

The Examiner also states that "applicant does not disclose the steps involved in removing any protective groups from the compound." This assertion also is not understood. The Examiner's attention is directed, for example, to Method D(iii) on page 29 of the specification. This discloses the reaction of a compound of formula II, in which R<sup>a</sup> is an ethyl ester group (*i.e.*, a protected COOH group) and R<sup>b</sup> is acetoxy (*i.e.*, a protected OH group), with a compound of the formula III to give a protected compound of the formula I. The protecting groups are removed sequentially in Method E (page 30), where the OH group is generated, and Example 1, where the COOH group is generated, and a compound of the formula (I) results.

This clearly constitutes the disclosure of an example of removal of protecting groups, and other deprotection steps, which may be desired for the preparation of other compounds, would be well within the general knowledge of the person skilled in this art. In this regard, other claims had been rejected in *Mayhew* based on the contention that the claims failed to recite the temperature of the zone of "cooled spelter or the function thereof" (188 USPQ at 358). However, the rejection of these claims was not sustained by the Court, noting:

Reading the claims, as they must be read, in the light of the specification, we think that the general function of the cooling zone is clear from the other recitations of the claims and that selection of the temperature of the zone would be within the ability of one of ordinary skill in the art attempting to follow the teaching of the specification. It is also apparent

that the temperature of the cooling zone would have to be regulated to meet varying conditions, such as the temperature of the main body of the bath, the thickness of the strip, the speed of its movement through the bath, etc.

(188 USPQ at 359). Similarly, in the present invention, the specific steps carried out to remove the protecting group is dependent on the nature of the protecting group that is involved. It is well within the knowledge and skill of the art to select appropriate protecting groups, and to select appropriate means for the removal of these protecting groups, particularly considering the guidance given in the specification.

In view of the above considerations, it is submitted that this ground for rejection of claim 8 is not supported by the circumstances of this application or the case law applied, and withdrawal of the ground for rejection is respectfully requested.

The Examiner has also newly rejected claim 8 under 35 U.S.C. § 112, second paragraph with respect to the phrase "reacting compounds." This ground for rejection has been overcome by the above amendment to claim 8 replacing "reacting compounds" with the phrase "reacting a compound" as suggested by the Examiner.

Method of treatment claims 11-17 have been rejected under 35 U.S.C. § 112, first paragraph. While applicant and the undersigned strongly disagree with the asserted bases for the rejection of these claims, method claims 11-17 have been cancelled for the sole purpose of expediting this application to allowance. The cancellation of these claims is without abandonment of the subject matter of these claims and with prejudice to applicants' right to present and prosecute the subject matter of these claims in one or more continuing applications.

***Conclusion***

Claims 1-7 and 9 have already been allowed, and it is believed that the grounds for rejection of claim 8 have been overcome by the foregoing amendment to this claim and the above remarks. Accordingly, all claims now pending in this application are believed to be in condition for allowance, and the allowance of this application is respectfully requested.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,  
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